assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1).

(ii) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).

(iii) A material that may be used to replace human skin (for example, a biological skin replacement material or synthetic skin replacement material).

(c) *Criteria for establishing device categories.* CMS uses the following criteria to establish a category of devices under this section:

(1) CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

(2) CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

(3) Except for medical devices identified in paragraph (e) of this section, CMS determines the cost of the device is not insignificant as described in paragraph (d) of this section.

(d) *Cost criteria.* CMS considers the average cost of a category of devices to be not insignificant if it meets the following conditions:

(1) The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.

(2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.

(3) The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service.

(e) *Devices exempt from cost criteria.* The following medical devices are not subject to the cost requirements described in paragraph (d) of this section, if payment for the device was being made as an outpatient service on August 1, 2000:

(1) A device of brachytherapy.

(2) A device of temperature-monitored cryoablation.

(f) *Identifying a category for a device.* A device is described by a category, if it meets the following conditions:

(1) Matches the long descriptor of the category code established by CMS.

(2) Conforms to guidance issued by CMS relating to the definition of terms and other information in conjunction with the category descriptors and codes.

(g) *Limited period of payment for devices.* CMS limits the eligibility for a pass-through payment established under this section to a period of at least 2 years, but not more than 3 years beginning on the date that CMS establishes a category of devices.

(h) *Amount of pass-through payment.* Subject to any reduction determined under § 419.62(b), the pass-through payment for a device is the hospital's charge for the device, adjusted to the actual cost for the device, minus the amount included in the APC payment amount for the device.

[66 FR 55856, Nov. 2, 2001, as amended at 67 FR 66813, Nov. 1, 2002; 70 FR 68728, Nov. 10, 2005; 74 FR 60680, Nov. 20, 2009]

Subpart H—Transitional Corridors

SOURCE: 65 FR 18542, Apr. 7, 2000, unless otherwise noted. Redesignated at 66 FR 55856, Nov. 2, 2001.

§ 419.70 Transitional adjustments to limit decline in payments.

(a) *Before 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished before January 1, 2002, for which the prospective payment system amount (as defined in paragraph (e) of this section) is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in paragraph (f) of this section), the amount of payment under this part is increased by 80 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.71 and the pre-BBA amount exceeds the product of 0.70 and the prospective payment system amount;

(3) At least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.63 and the pre-BBA amount, exceeds the product of 0.60 and the PPS amount; or

(4) Less than 70 percent of the pre-BBA amount, the amount of payment under this part shall be increased by 21 percent of the pre-BBA amount.

(b) *For 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2002, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 70 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.61 and the pre-BBA amount exceeds the product of 0.60 and the prospective payment system amount; or

(3) Less than 80 percent of the pre-BBA amount, the amount of payment under this part is increased by 13 percent of the pre-BBA amount.

(c) *For 2003.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2003, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 60 percent of the amount of this difference; or

(2) Less than 90 percent of the pre-BBA amount, the amount of payment under this part is increased by 6 percent of the pre-BBA amount.

(d) *Hold harmless provisions*—(1) *Temporary treatment for small rural hospitals before January 1, 2006.* For covered hospital outpatient services furnished in a calendar year before January 1, 2006, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is located in a rural area as defined in §412.64(b) of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act; and

(ii) Has 100 or fewer beds as defined in §412.105(b) of this chapter.

(2) *Temporary treatment for small rural hospitals on or after January 1, 2006.* For covered hospital outpatient services furnished in a calendar year from January 1, 2006 through December 31, 2012, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 95 percent of that difference for services furnished during CY 2006, 90 percent of that difference for services furnished during CY 2007, and 85 percent of that difference for services furnished during CYs 2008, 2009, 2010, 2011, and 2012 if the hospital—

(i) Is located in a rural area as defined in §412.64(b) of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;

(ii) Has 100 or fewer beds as defined in §412.105(b) of this chapter;

(iii) Is not a sole community hospital as defined in §412.92 of this chapter; and

(iv) Is not an essential access community hospital under §412.109 of this chapter.

(3) *Permanent treatment for cancer hospitals and children's hospitals.* In the case of a hospital described in §412.23(d) or §412.23(f) of this chapter for which the prospective payment system amount is less than the pre-BBA amount for covered hospital outpatient services, the amount of payment under this part is increased by the amount of this difference.

(4) *Temporary treatment for sole community hospitals located in rural areas for covered hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2004 and before January 1, 2006.* For covered hospital outpatient services furnished during cost reporting periods beginning on

or after January 1, 2004, and continuing through December 31, 2005, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is a sole community hospital, under § 412.92 of this chapter; and

(ii) Is located in a rural area as defined in § 412.63(b) or § 412.64(b), as applicable, of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act.

(5) *Temporary treatment for small sole community hospitals on or after January 1, 2009 and through December 31, 2009.* For covered hospital outpatient services furnished on or after January 1, 2009, and continuing through December 31, 2009, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital—

(i) Is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter; and

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter.

(6) *Temporary treatment for sole community hospitals on or after January 1, 2010, and through December 31, 2011.* For covered hospital outpatient services furnished on or after January 1, 2010, through December 31, 2011, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter.

(7) *Temporary treatment of small sole community hospitals on or after January 1, 2012 through December 31, 2012.* (i) For covered hospital outpatient services furnished on or after January 1, 2012 through December 31, 2012, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital—

(A) Is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter; and

(B) Has 100 or fewer beds as defined in § 412.105(b) of this chapter, except as provided in paragraph (d)(7)(ii) of this section.

(ii) For covered hospital outpatient services furnished on or after January 1, 2012 through February 29, 2012, the bed size limitation under paragraph (d)(7)(i)(B) of this section does not apply.

(e) *Prospective payment system amount defined.* In this section, the term ''prospective payment system amount'' means, with respect to covered hospital outpatient services, the amount payable under this part for these services (determined without regard to this section or any reduction in coinsurance elected under § 419.42), including amounts payable as copayment under § 419.41, coinsurance under section 1866(a)(2)(A)(ii) of the Act, and the deductible under section 1833(b) of the Act.

(f) *Pre-BBA amount defined*—(1) *General rule.* In this paragraph, the ''pre-BBA amount'' means, with respect to covered hospital outpatient services furnished by a hospital or a community mental health center (CMHC) in a year, an amount equal to the product of the reasonable cost of the provider for these services for the portions of the provider's cost reporting period (or periods) occurring in the year and the base provider outpatient payment-to-cost ratio for the provider (as defined in paragraph (f)(2) of this section).

(2) *Base payment-to-cost-ratio defined.* For purposes of this paragraph, CMS shall determine these ratios as if the amendments to sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act made by section 4521 of the BBA, to require that the full amount beneficiaries paid as coinsurance under section 1862(a)(2)(A) of the Act are taken into account in determining Medicare Part B Trust Fund payment to the hospital, were in effect in 1996. The ''base payment-to-cost ratio'' for a hospital or CMHC means the ratio of—

(i) The provider's payment under this part for covered outpatient services

furnished during one of the following periods, including any payment for these services through cost-sharing described in paragraph (e) of this section:

(A) The cost reporting period ending in 1996; or

(B) If the provider does not have a cost reporting period ending in 1996, the first cost reporting period ending on or after January 1, 1997, and before January 1, 2001; and

(ii) The reasonable costs of these services for the same cost reporting period.

(g) *Interim payments.* CMS makes payments under this section to hospitals and CMHCs on an interim basis, subject to retrospective adjustments based on settled cost reports.

(h) *No effect on coinsurance.* No payment made under this section affects the unadjusted coinsurance amount or the coinsurance amount described in § 419.41.

(i) *Application without regard to budget neutrality.* The additional payments made under this section—

(1) Are not considered an adjustment under § 419.43(f); and

(2) Are not implemented in a budget neutral manner.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 69 FR 832, Jan. 6, 2004; 69 FR 65863, Nov. 15, 2004; 71 FR 68228, Nov. 24, 2006; 72 FR 66933, Nov. 27, 2007; 73 FR 68814, Nov. 18, 2008; 74 FR 60681, Nov. 20, 2009; 75 FR 72265, Nov. 24, 2010; 76 FR 74583, Nov. 30, 2011; 77 FR 68559, Nov. 15, 2012]

PART 420—PROGRAM INTEGRITY: MEDICARE

Subpart A—General Provisions

Sec.

Subpart B [Reserved]

Subpart C—Disclosure of Ownership and Control Information

Subpart D—Access to Books, Documents, and Records of Subcontractors

Subpart E—Rewards for Information Relating to Medicare Fraud and Abuse, and Establishment of a Program to Collect Suggestions for Improving Medicare Program Efficiency and to Reward Suggesters for Monetary Savings

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 44 FR 31142, May 30, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 420.1 Scope and purpose.

This part sets forth requirements for Medicare providers, intermediaries, and carriers to disclose ownership and control information. It also deals with access to records pertaining to certain contracts entered into by Medicare providers. These rules are aimed at protecting the integrity of the Medicare program. The statutory basis for these requirements is explained in each of the other subparts.

[51 FR 34787, Sept. 30, 1986]

§ 420.3 Other related regulations.

(a) *Appeals procedures.* Part 498 of this chapter sets forth the appeals procedures available to providers whose provider agreements CMS terminates for failure to comply with the disclosure of information requirements set forth in subpart C of this part.